

Environmental Protection Agency

§ 26.1303

(c) Information about how subjects will be recruited, including any advertisements proposed to be used.

(d) A description of the circumstances and methods proposed for presenting information to potential human subjects for the purpose of obtaining their informed consent.

(e) All correspondence between the IRB and the investigators or sponsors.

(f) Official notification to the sponsor or investigator, in accordance with the requirements of this subpart, that research involving human subjects has been reviewed and approved by an IRB.

Subpart L—Prohibition of Third-Party Research Involving Intentional Exposure to a Pesticide of Human Subjects who are Children or Pregnant or Nursing Women

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1201 To what does this subpart apply?

This subpart applies to any research subject to subpart K of this part.

[78 FR 10544, Feb. 14, 2013]

§ 26.1202 Definitions.

The definitions in § 26.1102 shall be applicable to this subpart as well. In addition, the definitions at 45 CFR 46.202(a) through (f) and at 45 CFR 46.202(h) are applicable to this subpart. In addition, a child is a person who has not attained the age of 18 years.

§ 26.1203 Prohibition of research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

Notwithstanding any other provision of this part, under no circumstances shall a person conduct or support research covered by § 26.1201 that involves intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

[71 FR 36175, June 23, 2006]

Subpart M—Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1301 To what does this subpart apply?

This subpart applies to any person who submits to EPA on or after April 15, 2013 either of the following:

(a) A report containing the results of any human research for consideration in connection with an action that may be performed by EPA under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a).

(b) A report containing the results of any human research on or with a pesticide for consideration in connection with any action that may be performed by EPA under any regulatory statute administered by EPA.

[78 FR 10544, Feb. 14, 2013]

§ 26.1302 Definitions.

The definitions in § 26.102 apply to this subpart as well.

[71 FR 6168, Feb. 6, 2006, as amended at 78 FR 10544, Feb. 14, 2013]

§ 26.1303 Submission of information pertaining to ethical conduct of completed human research.

Any person who submits to EPA data derived from human research covered by this subpart shall provide at the time of submission information concerning the ethical conduct of such research. To the extent available to the submitter and not previously provided to EPA, such information should include:

(a) Copies of all of the records relevant to the research specified by § 26.1115(a) to be prepared and maintained by an IRB.

(b) Copies of all of the records relevant to the information identified in § 26.1125(a) through (f).

(c) Copies of sample records used to document informed consent as specified by § 26.1117, but not identifying any subjects of the research.